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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,628	09/29/2003	Luciano Tosato	1767	4002
7590 Walter H. Schneider 21530 Beechwood Rd. Circleville, OH 43113				
EXAMINER CAMPBELL, VICTORIA P				
ART UNIT		PAPER NUMBER		
3763				
MAIL DATE		DELIVERY MODE		
05/29/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/679,628

Applicant(s)

TOSATO, LUCIANO

Examiner

VICTORIA P. CAMPBELL

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
4a) Of the above claim(s) 11 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-10 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species A, Figs. 1-4, defined by applicant as claims 1-10 in the reply filed on March is acknowledged.

This is the initial Office Action based on the 10/679628 application filed September 29, 2003. Claims 1-10 as elected are currently pending and considered below.

Specification

2. The abstract of the disclosure is objected to because there is no ending punctuation on the sentence; it should end in a period -- . --. Correction is required.
See MPEP § 608.01(b).

Claim Objections

3. Claims 1-10 are objected to because of the following informalities:
Claims 1-10 do not begin with an article such as "A" or "The".
Claims 2-10 contain various instances of "the said". Only one of "the" or "said" needs to be used to properly refer back to a particular part.
Claim 5, line 2: "characterized" is misspelled.
Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by USPN 4,341,211 to Kline.

Regarding the above claims, Kline discloses the following:

A disposable vaginal cannula (16) designed to deliver drugs with different compositions simultaneously, characterized in that it comprises means (29, 33) designed to receive two or more different products to be administered and means (23, 26) designed to expel the said products simultaneously or successively, wherein it comprises a barrel (17) designed to contain a predetermined quantity of two or more products, including one semi-solid (29), means (23, 26) designed to exert a thrust on the said products to expel them, a set of openings (20, 21) being provided in correspondence with the parts of the said container in which the said products are situated, which allow the products to exit as a result of the thrust exerted on them, and which allow air to exit when the plunger is inserted, wherein the barrel is fitted with a separator (23) designed to prevent the said products from coming into contact with one another before use, the said separator (23) being able to move inside the said container so that it slides along the cannula as a result of the thrust applied to the products. Kline further discloses one open end (20) with a seating (33) designed to contain a tablet (10)

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of a product to be administered, said separator (23) which can slide inside the said cannula, and being equipped with means (24) designed to engage the said tablet to control its expulsion, as well as a covering sheath (38) designed to be fitted over the distal end of the cannula, and means to prevent expulsion of the product prior to use (31).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kline in view of USPN 5,823,988 to Orenga et al.

Regarding claims 7 and 8, Kline discloses the invention of claim 5 as described above, but fails to teach or disclose ridges on the interior to support the separator or tablet. Orenga et al teach a projection (48) that would be capable of engaging either the

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separator or tablet to maintain a position within the applicator. Kline and Orenga et al are analogous art because they are from the same field of endeavor/problem solving area of applicators. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Kline and Orenga et al before him or her to modify the applicator of Kline to include the projection of Orenga et al because doing so would help to maintain the parts in their separated position within the applicator. Therefore, it would have been obvious to combine Kline with Orenga et al to obtain the invention in the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763